REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claims 43-45 have been amended to recite that the insulin is selected from the group consisting of natural human insulin, recombinant human insulin, extracted bovine insulin, extracted porcine insulin, recombinant bovine insulin, recombinant porcine insulin, and combinations thereof. Support for this amendment can be found specifically in paragraph [0067] of the originally filed specification. Claim 44 has been further amended to recite that the microparticles are porous and that the insulin is permeated in the pores of the microparticles. Support for this amendment can be found specifically in paragraphs [0074] through [0076]. New claims 46 and 51 have been added. Claims 27-37, 41, and 43-51 are pending.

Rejections under 35 U.S.C. §112

Claims 27-37, 41, and 44-45 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for use of the claim term "act." Claims 44 and 45 have been amended to remove the noted language. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 27-37, 41, and 43-45 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Although Applicant does not agree with the rejection, claims 43-45 have been amended to recite that the insulin is selected from the group consisting of natural human insulin, recombinant human insulin, extracted bovine insulin, extracted porcine insulin, recombinant bovine insulin, recombinant porcine insulin, and combinations thereof. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. §102

Claims 27-29, 35, 41, and 43-45 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schröder (Methods in Enzymology, 1985). Applicant respectfully traverses this rejection.

The Examiner has mischaracterized the disclosure of Schröder. The Examiner alleges that Schröder discloses on page 117, 3rd paragraph, that there are pores in the polymer matrix. This section of Schröder discusses previous attempts to entrap proteins in nonbiodegradable polymers and does not relate to the dextran microparticles discussed later by Schröder.

The Examiner alleges that Schröder discloses in Figure 1 that the crystalline polymer matrix has pores. Applicant admits that Figure 1(b) shows particles entrapped in the matrix, as the Figure legend expressly states. Nothing in Figure 1(b) shows particles contained in pores open to the outside of the crystalline structure.

The Examiner alleges that Schröder discloses in Figure 2 that the insulin is released over time. This does not indicate it is released from pores.

In reality, at page 120 (under the heading "Crystallized Carbohydrate Spheres (CCS) for Slow Release"), Schröder discloses that his composition relates totally to **entrapment** of substances for slow release. The following text discloses that the dextran and the active substance "do be entrapped" are co-dissolved and then precipitated to form spheres wherein the active substance is entrapped therein. The Examiner's attempt to characterize Schröder as teaching porous structures where the active agent may be released through the pores is a misplaced attempt to conform the art to the present claim, and this is improper. The full context of Schröder cannot be separated from the clear and unequivocal disclosure that, "Entrapment of substances in carbohydrate spheres for slow release was performed according to the [stated] procedure" (page 120, first and second sentence of first full paragraph).

Schröder does not disclose a composition wherein none of the insulin is encapsulated by the porous crystallized dextran microparticles (claims 43 and 45). Likewise, Schröder does not disclose a composition wherein the insulin is permeated in the pores of the crystallized dextran microparticles (claim 44). Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 27-29, 35, 41, and 43-45 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schröder (U.S. Patent No. 4,713,249). Applicant respectfully traverses these rejections.

The Examiner alleges Schröder teaches release of insulin over time and, as such, the Schröder microparticles do not encapsulate the insulin. This portion of Schröder is part of the

Background wherein Schröder is reciting the known, desirable properties of polymer depot matrices. This in no way teaches that the Schröder encapsulated insulin is slowly released over time. In fact, the Examiner has misquoted Schröder. The cited section actually states that the polymer should be capable of releasing the active substance. The Examiner has used hindsight to improperly add the words "over time." Release can be by the degradation of the Schröder carbohydrate shell to release the entire content encapsulated therein, and the Examiner has pointed to nothing in Schröder teaching otherwise.

The Examiner has tried to differentiate enclosing versus encapsulating. Regardless of the Examiner's misguided attempt to parse words, the reality is that Schröder teaches co-dissolving the dextran and the insulin and precipitating the solution so that the insulin is provided within the formed spheres to enclose (or entrap) the insulin. This is a clear teaching of encapsulation whether or not the Examiner wants to accept the clear teaching of the document.

Since Schröder does not disclose a composition wherein none of the insulin is encapsulated by the porous crystallized dextran microparticles (claims 43 and 45), and since Schröder does not disclose a composition wherein the insulin is permeated in the pores of the crystallized dextran microparticles (claim 44), Applicant submits the present rejection is improperly applied. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Rejections under 35 U.S.C. §103

Claims 32, 33, and 37 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Moriyama (Journal of Controlled Release, 1996). Claims 31 and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Ecanow (U.S. Patent No. 4,963,526). Claims 30 and 34 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Clark et al. (U.S. Patent No. 5,783,556). Applicant respectfully traverses these rejections.

As pointed out above, Schröder does not disclose a composition wherein none of the insulin is encapsulated by the porous crystallized dextran microparticles (claims 43 and 45), and Schröder does not disclose a composition wherein the insulin is permeated in the pores of the

crystallized dextran microparticles (claim 44). Since all of the presently rejected claims depend from claim 44, and since none of the secondary cited references cures this deficiency of Schröder, Applicant submits the present rejections have been improperly applied. Thus, Applicant respectfully requests reconsideration and withdrawal of the present rejections.

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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